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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,425	11/15/2000	Leonard Presta	P1726R1P1	3384

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,425

Applicant(s)

PRESTA, LEONARD

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-63 and 80-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-63 and 80-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/04 has been entered.

Following entry of the amendment claims 60-63 and 80-82 are pending. The amendment has necessitated the following new grounds of rejection

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

Applicant's amendment has inserted the modifier "ex vivo" in order to overcome the previously stated lack of utility rejection and has urged that specification pages 38-40 show a utility for the claimed complexes in binding assays for "evaluating the binding affinity of the polypeptide to the receptor."

The examiner, however, fails to find that the claimed complexes of a polypeptide having an altered Fc polypeptide and an Fc. Gamma. R allotype are therein disclosed. Specifically the complexes that are formed in the assay consist of more components. For example page 38, lines 10-15 teach a trimolecular immune complex of a) the Fc region containing polypeptide, b) a first target molecule..., and c) a second target

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molecule... This trimolecular immune complex is what is then used to form a complex with the Fc. Gamma. R. Applicant's claim on the other hand would encompass a complex that consists merely of component a), i.e. The Fc region containing polypeptide per se, and the Fc. Gamma. R. Applicant's claims thus encompass embodiments not originally disclosed.

At the minimum, applicant could claim a complex formed of components a) and b), which are then, in turn, complexed to the Fc. Gamma. R. See disclosure at page 38, lines 27-30.

The lack of utility/ how to use rejection is maintained infra.

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicant has disclosed no utility for the claimed complexes

Claims 60-63 and 80-82 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a use asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant has urged that the rejection has been overcome by insertion of "ex vivo" and by arguing that pages 38-40 teach that the claimed complex would have a use in assays for evaluating binding affinity. This argument is not persuasive because, as noted supra concerning new matter, the claimed complexes are not those that are formed in the disclosed assays, at pages 38-40, for the evaluation of binding affinity.

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Indeed applicant's teachings indicate that the binding affinity of an Fc containing polypeptide per se for a Fc. Gamma. R is "relatively weak" (page 38, line 9). Applicant thus found that assays that would form the claimed complex were not suitable and teaches away therefrom. Given these teachings, the examiner does not consider the arguments presented for utility to be consistent with the specification disclosure.

Applicant's urgings filed on 4/21/04 have been considered but are unconvincing of utility.

The prior art rejections of record are maintained infra.

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 102((b) or (e)) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Idusogie et al (WO 99/51642 or US 6,242,195).

Claims 60-63 and 80-82 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Idusogie et al (6,528,624).

Applicant considers that the rejections of record have been overcome by inserting "ex vivo" as a claim limitation not taught by Idusogie et al. The examiner sees the limitation of "ex vivo" as being essentially a product by process limitation; as such the nature of the noncovalent bond must be considered for what it is per se and not how it may have been formed. The office considers that there is no material difference in the nature of the noncovalent bonds formed between an Fc containing polypeptide and Fc. Gamma. R in vivo and ex vivo. Thus the nature of the noncovalent bond that would be formed in vivo, as taught by Idusogie et al, is the same as that of the noncovalent

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bond that would be formed ex vivo. The teachings of Idusogie et al thus remain applicable.

It is to be noted that nothing in applicant's amended claims requires that the complex of the Fc polypeptide and Fc receptor exist as an isolated complex ex vivo (or in vivo). The limitation "ex vivo" merely disclosed the nature of the non covalent bond, and as indicated supra, the nature of the noncovalent bond is the same when it is formed in vivo. Since applicant's claim scope is open, the claim still reads upon the Fc containing polypeptides of Idusogie et al that are non-covalently bound to Fc. Gamma. R on cells in vivo.

Applicant's urgings filed 12/21/04 have been considered but are unconvincing that the prior art rejection should be withdrawn.

Applicant is advised that should claim 80 be found allowable, claim 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
May 20, 2005


DAVID SAUNDERS
PRIMARY EXAMINER
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